

PATENT COOPERATION TREATY

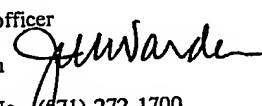
PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 10 MAY 2004

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Applicant's or agent's file reference	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
57436WO003			
International application No.	International filing date (day/month/year)	Priority date (day/month/year)	
PCT/US02/40949	23 December 2002 (23.12.2002)	31 December 2001 (31.12.2001)	
International Patent Classification (IPC) or national classification and IPC			
IPC(7): G01N 1/00 and US Cl.: 437/174			
Applicant			
3M INNOVATIVE PROPERTIES COMPANY			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			
Date of submission of the demand		Date of completion of this report	
04 June 2003 (04.06.2003)		20 April 2004 (20.04.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Jill Warden  Telephone No. (711)-272-1700	

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US02/40949

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-8 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 9 and 10, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the drawings:
pages 1, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/40949**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>2,3,6,7,9,11,12,13</u>	YES
	Claims <u>1,4,5,8,10</u>	NO
Inventive Step (IS)	Claims <u>6,7,9,13</u>	YES
	Claims <u>1-5,8,10-12</u>	NO
Industrial Applicability (IA)	Claims <u>1-13</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1,4,5,8 and 10 lack novelty under PCT Article 33(2) as being anticipated by Beecham (U.S. Pat. 5,876,926). Beecham teaches a method, apparatus, and system for verification of human medical data. The method includes the steps of collecting a sample, sealing the sample, shipping the sample to a processing facility, processing the sample, and communicating the results to the user. Beecham teaches a wide variety of testing methods. One embodiment of their invention which is most relevant to the instant claims is recited in column 12, line 60 through column 13, line 35 and details the collection and analysis of a hair sample. The hair sample is collected and sealed into sample container in the presence of the donor and a representative of the testing facility or the entity requesting the test. The sample is then sent to a lab for testing. The results of the testing on the hair sample are then supplied via database where the data on the sample is stored until it can be accessed by either the donor or the entity requesting the sample. Beecham also teaches the collection of urine, breath, oral, blood, and fingernail samples (column 15). Beecham discloses genetic analysis on biological samples in column 5, lines 28-34.

Claims 2,3,11 and 12 lack an inventive step under PCT Article 33(3) as being obvious over Beecham (U.S. Pat. 5,876,926) in view of Oxley (5,423,792). Beecham teaches every element of claims 2, 3, 11, and 12 except for the use of reagents in conjunction with the sample processing device and tamper evident sealing. Oxley (5,423,792) teaches a biological collection system. The system includes a container having a port opening for receipt of the specimen, means for sealing the container, means for separating portions of the sample into separate compartments, and identification elements (Abstract). The system includes a tamper indicating means which can be applied after collection of the sample (column 7, lines 8-33). Oxley also teaches the use of analytical reagents in conjunction with the sample container for use in prescreening tests. These reagents may be added to the sample container either before or after the collection of the sample (column 7, line 64 - column 8, line 32). It would have been obvious to one of ordinary skill in the art at the time to combine the tamper prevention elements and reagents of Oxley with the method of Beecham. One would add the tamper prevention elements in order to prevent someone from tampering with the sample during shipment of the sample. This would be extremely important when shipping criminal or medical samples as is taught in Beecham. One would add the use of prescreening reagents in order to do crude on-site analysis of the sample before it is shipped to the laboratory for further analysis.

Claims 6,7,9 and 13 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of using a sample processing device comprised of loading the sample, sealing the sample with pressure sensitive adhesive (cl. 13), shipping the sample to the processing facility, processing the sample by Sanger sequencing or electrophoresis (cls. 6, 7), communicating the results to the user and then shipping the sample back to the user (cl. 9).

Claims 1-13 have industrial applicability as defined by PCT Article 33(4). The method is useful in the area of biological sample analysis.

----- NEW CITATIONS -----